

**Appl. No.** : **09/993,874**  
**Filed** : **November 14, 2001**

### **REMARKS**

Claims 6, 10 and 11 have been canceled without prejudice.

Claim 1 has been amended to clarify the invention. No new matter has been entered thereby.

Claim 7 has been amended so as to depend solely from Claim 1.

Claims 3 and 9 have been withdrawn by the Examiner from consideration as being directed to a non-elected invention.

The amendment to the drawings requested here is requested solely in order to correct a clerical error. Support for the correction can be found in SEQ ID No: 1. Approval of drawing changes is respectfully requested.

No new matter has been added, and Applicant respectfully requests entry of the amendments and reconsideration of the application in view of the amendments and of the following remarks.

#### Specification

The Examiner has approved cancellation of Figures 1 and 2. Applicant notes that in his Amendment filed February 17, 2004, Applicant withdrew the request to delete Figures 1 and 2. In view of that withdrawal, Applicant requests that cancellation of Figure 2 be rescinded.

The Examiner has objected to the specification because the description of Figures 1A – 1C on page 4, lines 4-6 indicates SEQ ID NO: 1. The Examiner has noted that the nucleotide sequence shown at the Figures differs from that of SEQ ID NO: 1. Applicant accedes to the cancellation of original Figure 1 and herewith submits amended Figure 1, which contains the sequence shown in SEQ ID NO: 1.

#### Claim Objections

The Examiner has objected to Claims 6-8, 10, and 11 under 37 C.F.R. § 1.75(c) as being of improper dependent form. Applicant has canceled Claims 6, 10, and 11 without prejudice, and as a result of the present amendment, Claims 7 and 8 no longer depend from canceled Claim 6. This objection is therefore no longer applicable.

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Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Examiner has rejected Claims 1, 6-8, 10 and 11 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Specifically, although the Examiner notes that “there is support in the specification for ‘a maximum  $\lambda$  = 549 nm,’” the Examiner was unable to locate support in this specification for a maximum  $\lambda$  of “approximately” 549 nm. Applicant respectfully disagrees with the Examiner’s rejection and requests reconsideration for the reasons stated below.

It is well known to those of skill in the art that the measurement of electromagnetic emission spectra, for example using a spectrofluorometer, is subject to variation in results depending upon, among other things: (1) the type of instrument employed to conduct the measurement, (2) accurate calibration of the instrument, (3) problems with variation in equipment employed (such as cuvettes), (4) the presence of non-fluorescent substances in a sample, (5) solvent volume employed, (6) solid interference from particulates, (7) the presence of trace organic chemical contamination, or (8) the temperature and pH conditions under which the measurement is taken. See Manual for Using Fluorescent Microspheres to Measure Regional Organ Perfusion, chs. 2-3, pp. 2-3, 2-5, 2-8, 3-5, 3-6, 3-7 (Fluorescence Microsphere Resource Center, Univ. of Washington 1999) (at <http://fmrc.pulmcc.washington.edu/DOCUMENTS/FMRCMAN99.pdf>). Given this well-known variation in the results of emission spectra measurement, one of skill in the art would understand that the present specification’s disclosure of a maximum  $\lambda$  of 549 nm in actuality means a maximum  $\lambda$  of approximately 549 nm, because absolute accuracy in the results of the measurement is effectively impossible in the art. For this reason, applicant submits that the claim limitation of a luciferase emitting at “a maximum  $\lambda$  of approximately 549 nm” was within the scope of the invention as conceived by the applicants when the application was filed. Applicant respectfully requests withdrawal of this rejection.

The Examiner has rejected Claims 6-8, 10, and 11 under 35 U.S.C. § 112, first paragraph, because of the Examiner’s view that the specification does not reasonably provide enablement for a DNA that is 90% identical to SEQ ID NO: 1. By this paper, applicant has canceled Claims

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6, 10, and 11 without prejudice, and has readjusted the dependencies of Claim 7 and 8 so as to eliminate dependency from canceled Claim 6. This rejection is therefore no longer applicable.

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 1, 6-8, 10, and 11 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, because of the Examiner's view that "[t]he metes and bounds of the term 'approximately' are not defined in the specification and can mean different ranges in the art." Applicant respectfully disagrees with this rejection. To those of skill in the art of measuring electromagnetic emission spectra, using for example a spectrofluorometer, the metes and bounds of the term "approximately," in the context of a claim limitation of "a maximum  $\lambda$  of approximately 549 nm," are in fact clear: the term "approximately" simply refers to that range of variation which is ordinarily to be expected as a result of the differences in measurement method or instrument employed, as described above. Applicant submits that, in view of this knowledge of one of ordinary skill in the art, the claim term "approximately" is not unclear. See In re Moore, 439 F.2d 1232, 1235, 169 U.S.P.Q. 236, 238 (C.C.P.A. 1971) ("It is here where the definiteness of the language employed must be analyzed—not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art."). For this reason, applicant respectfully requests withdrawal of this rejection.

The Examiner has rejected claims 6 through 8, 10, and 11 as unclear based on the recital in those claims of "at least 90% identity" without indicating to which sequence the claim sequence is identical. By this paper, applicant has canceled claims 6, 10, and 11 without prejudice, and has adjusted the dependencies of Claim 7 and 8 so that they no longer depend from canceled Claim 6. This rejection is therefore no longer applicable.

The Examiner has rejected Claim 11 for insufficient antecedent basis. By this paper, applicant has canceled Claim 11 without prejudice. Therefore, this rejection is no longer applicable.

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### CONCLUSION

In light of the Applicant's amendments to the claims and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

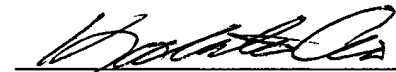
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 14, 2004

By:



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